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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,055

07/09/2003

Amarpreet S. Sawhney

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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

08/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,055	Applicant(s) SAWHNEY, AMARPREET S.	
	Examiner John Pak	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11, 20-22, 24, 25, 37-40 and 73-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11, 20-22, 24, 25, 37-40 and 73-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/10/07, 8/29/07</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-5, 11, 20-22, 24-25, 37-40 and 73-76 are now pending in this application.

Applicant's election without traverse of the invention of Group III in the reply filed on 4/24/2008 is acknowledged. Independent claim 1 has been amended to correspond to the election.

Applicant is advised of the following. It is recognized that the amendatory feature in claim 1 as shown below is likely derived from the discussion conducted before the issuance of the last Office action between the Examiner and applicant's attorney. See the "Claim Amendment for Discussion – Draft Copy" from the Examiner's fax of 3/25/2008, which is of record in this case as an attachment to the Interview Summary Record of the same date –

~~wherein the hydrogel, at the substantially less than equilibrium level of hydration, has a shape selected from the group consisting of a rod, a sphere, a block, a sheet, a tube, and a sheet rolled from one edge to another to form a roll, with the hydrogel having dimensions to pass through a tube having an inner diameter of no more than about 1.5 mm.~~

Applicant was advised in the fax that further patentability determination was required. Here, upon further review and reconsideration, it has been determined that this feature, in conjunction with the "pass through" feature, constitutes new matter. Full rationale is set forth below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11, 20-22, 24-25, 37-40 and 73-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As noted above, the amended independent claim 1 now requires the covalently crosslinked hydrogel polymerized from at least one synthetic hydrophilic polyethylene glycol macromer to have a shape selected from the group consisting of a rod, sphere, block, sheet, tube and a sheet rolled from one edge to another to form a roll, with the hydrogel having dimensions to pass through a tube having an inner diameter of no more than about 1.5 mm.

Upon further review and reconsideration, the originally filed disclosure does not appear to provide adequate descriptive support for such a claim feature. The following is the only mention of 1.5 mm in the original disclosure (specification page 36) –

Example 12

Use of a Hydrogel Plug to Close a Bronchial Fistula

A hydrogel rod is formed as described in Example 8, except that the rod is formed in a mold 5 mm in diameter and has a 50 cm long suture embedded in it. The hydrogel is dried to a diameter of about 1.5 mm. The hydrogel may be placed in a catheter comprising a hollow flexible tube with a distal opening and a proximal end that remains outside the patient. The distal end may be maneuvered through the operating channel of a bronchoscope and into the bronchial tree to implant the hydrogel rod.

First, the disclosure here is limited to a rod with no further guidance that the dimension applies to other shapes such as sphere, block, sheet, tube. Second, the rod is **dried to a diameter** of about 1.5 mm, but this is not the same thing as having a dimension to **pass through a tube** having an inner diameter of no more than 1.5 mm. As a result, not even a rod with the presently claimed feature finds adequate descriptive support from the originally filed disclosure, let alone the other claimed shapes such as sphere, block, sheet, tube.

Additionally, original claim 53 discloses a sterilized, biodegradable (both features are not recited in the instant claims) hydrogel, which has a shape for passage through an inner diameter of a catheter or hollow needle into the body:

53. A medical implant for use in a lumen or void of a body of a patient comprising:
a sterilized covalently crosslinked biodegradable hydrogel polymerized from at least one macromer, the hydrogel having a shape for passage through an inner diameter of a catheter or hollow needle into the body, and having a substantially less than equilibrium level of hydration for undergoing a volumetric expansion of at least about 20% in physiological fluid to occlude the lumen or void after swelling with a fluid from the body.

The original disclosure does not convey that the shape for passage through an inner diameter of a catheter or hollow needle into the body includes rod, block, sheet and tubes. The original disclosure also does not convey that the inner diameter of the catheter tube is no more than 1.5 mm. Further, instant claims do not require that the

hydrogel has a shape that is suitable to be directly administered through a catheter or hollow needle into the body.

For these reasons, all claims fail to find adequate descriptive support from the originally filed disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/
Primary Examiner, Art Unit 1616